Background for EPA Internal Use

Ex. 5 - Deliberative Process

Back-Pocket Qs and As

Why would EPA now regulate a GE mosquito used for population control?

Ex. 5 - Deliberative Process

Why is the question of which agency will regulate GE mosquitoes being addressed at this time as part of the Coordinated Framework Update effort? Why not when companies first indicated they were developing GE mosquitoes?

Ex. 5 - Deliberative Process

How does EPA regulate pesticides?

Ex. 5 - Deliberative Process

# Ex. 5 - Deliberative Process

**Does USDA play a role in the regulation of insects?**

# Ex. 5 - Deliberative Process

**How do *Wolbachia* mosquitoes currently being regulated by EPA for population control differ from the GE mosquito?**

## Ex. 5 - Deliberative Process

**The Oxitec GE mosquito is genetically engineered** in such a way that the mosquito larvae cannot grow into mature adults in the environment. Both approaches are intended to control mosquito populations by preventing successful reproduction, but accomplish this in different ways. Both focus on making changes to male mosquitoes that would then be released into the wild to mate with "wild" female mosquitoes. T**he Oxitec mosquito is genetically engineered; the Wolbachia-infected mosquito is not.** Only the female mosquitoes bite humans; male mosquitoes feed on flower nectar.

**How did it happen that one product intended to lower the number of mosquitoes in the environment is currently being reviewed by EPA as a pesticide, while another mosquito product that is also intended to lower the mosquito population, up until this action, has been reviewed by FDA?**

Both of these types of products are unique and work differently from the types of products seen in the past. Both FIFRA (administered by EPA) and FFDCA (administered by FDA) arguably could be used to regulate them. FDA decided to regulate the Oxitec mosquito as a new animal drug. EPA could not then regulate it as a pesticide under FIFRA. Ultimately, FDA and EPA came to the realization that products such as the Oxitec mosquito that are genetically engineered for population control purposes should be subject to EPA's jurisdiction as pesticides under FIFRA. On the other hand, Wolbachia is a bacterium that has long been regulated by EPA under FIFRA, and EPA and FDA agreed that both Wolbachia and Oxitec mosquitoes should be regulated by EPA.

**Why do we need these mosquito products when chemical pesticides can be used to kill mosquitoes?**
The use of chemical insecticides to target mosquitoes can be effective, but is often expensive and can be difficult to implement in urban areas where human exposure and potential sensitivity to the pesticide are important considerations.

**If the GE mosquito had gone to EPA first, would it already have a final determination?**
That is a hypothetical question and not really possible to answer. EPA's regulatory process under FIFRA has timeframes driven by statute to review and make decisions on pesticide applications. An applicant typically applies first for an Experimental Use Permit (EUP) to generate the data necessary to support the registration. Once a complete EUP application is received, the agency has 7 months to reach a decision on the testing. After sufficient data have been collected in field testing (these may range from a few months to several years depending on the types of data to be generated), the applicant typically then applies for a registration. Once a registration application is received, the agency has 13-25 months to complete its review. The 25-month estimate provides for input from nationally recognized technical experts via the EPA's FIFRA Scientific Advisory Panel when the Agency deems such input appropriate. In sum, from start to finish, the EPA process may take 2-4 years if all the data needed are submitted in a timely fashion.

**How does this realignment of regulatory responsibility affect the potential use of these mosquitoes in countering the Zika outbreak in the United States?**
The realignment of responsibilities will not affect the potential use of these mosquitoes in countering the Zika outbreak in the United States.

**What does this mean for the developer of a GE mosquito, Oxitec, whose product is currently under review at FDA? Does this mean that Oxitec will have to go through additional review at EPA?**
As the agencies realign their programs, the agencies will continue to work closely together to ensure a smooth realignment process. EPA and FDA reached out to Oxitec to initiate several discussions to help expedite the potential submission of a FIFRA registration application to help ensure EPA's review will be as expeditious as possible.